

**REMARKS**

Claims 124-134 are pending in the application. Claim 128-134 are withdrawn by the examiner. Claim 124 is amended by deleting the term "about" for clarity. No new matter has been added. The office action is discussed below.

***Election/Restriction:***

On pages 2-3 of the Office Action, the examiner has withdrawn claims 128-134 allegedly as being directed to a non-elected invention. The examiner also has set forth a requirement between claims reciting "melting" and "pre-annealing." Applicants respectfully disagree with the examiner and traverse the rejection. Applicants note that the requirement is non-sensical because "pre-annealing" is a synonym for "melting" according to US Patent 6,562,540 (Saum *et al.*, the '540 patent). See Saum *et al.* for example, col. 4, lines 23-25, col. 6, lines 35-38, describe pre-annealing of UHMWPE at a temperature greater than about 280°C (which is above the melting point of the UHMWPE). Withdrawal of the restriction requirement and consideration of claims 128-134 are solicited.

***Withdrawal of Saum as a prior art:***

Applicants thank the examiner for withdrawal of Saum as a prior art on the basis that the application is entitled to priority dates of February 13, 1996 (08/600,744) and October 2, 1996 (08/726,313).

***Claim Rejections - 35 U.S.C. § 112, First and second paragraphs:***

On pages 3-5 of the Office Action, the examiner has rejected claims 124-127 allegedly for failing to written description requirement. Applicants respectfully disagree with the examiner and submit that the claims are fully supported by the specification.

Applicants refer to above arguments that the term "pre-annealing" is a synonym for "melting", thus, the term is supported by the specification.

Regarding the terms "temperature greater than ambient temperature and less than the decomposition temperature" and "a period of time greater than about 30 minutes", applicants refer that the examiner has admitted on page 4 of the Office Action that the priority application discloses methods wherein polyethylene is heated at or above its melting temperature for about 5 minutes to about 3 hours. The examiner also has acknowledged that the priority application discloses heating to about 175°C (which is well known as a temperature that is less than the decomposition temperature of UHMWPE) and cooling the heated and irradiated polyethylene.

Regarding the range limitation, applicants point out that the duration of "30 minutes" is within the range of "about 5 minutes to about 3 hours" as described above. Therefore, the range limitation for a "period of time greater than about 30 minutes" is fully supported by the specification (See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), MPEP 2163.05 III at 2100-189 to 190 (Rev. 3, August 2005)).

Moreover, for additional clarity, applicants amend claim 124 by deleting the term "about". Withdrawal of the written description rejection is therefore requested.

***Claim Rejections - 35 U.S.C. § 102:***

On page 5 of the Office Action, the examiner has rejected claims 124-127 allegedly as being anticipated by Salovey (US 6,281,264, filed January 20, 1995). Applicants respectfully disagree with the examiner and submit that:

Applicants, previously in a related application (see US Serial No. 10/197,263, filed July 18, 2002), have provided declarations pursuant to 37 C.F.R. § 1.131 evidencing completion of the claimed invention prior to January 20, 1995. Accordingly, the Salovey '264 patent is not prior art against applicants' claims.

As described above, the claims are entitled to section 120 priority dates of February 13, 1996 and October 2, 1996. Although a patent applicant need not show completion of every embodiment of an invention in a Rule 131 declaration<sup>\*</sup>, the declaration provided by applicants contains data showing the completion of both the MIR and CISM embodiments of the invention prior to January 20, 1995.

Applicants also submit that Salovey discloses low dose irradiation (between 2.5 to 4.0 Mrad; see col. 5, line 59) for sterilization of finished or packaged products. Salovey specifically concentrates on chemical cross-linking of UHMWPE (see Abstract; col. 7, lines 15-61). Therefore, Salovey does not anticipate the claimed invention.

Applicants therefore request withdrawal of the rejection based upon the '264 patent.

On page 6 of the Office Action, the examiner has rejected claims 124-127 allegedly as being anticipated by Shalaby (US 5,824,411, filed August 20, 1993). Applicants respectfully disagree with the examiner and submit that:

Due to the filing dates of the Shalaby '411 patent, the examiner is reminded that the rejection should have only been made with the approval of the Technology Center Director. See MPEP §§ 1003; 2307.02 (August 2001).

Applicants also submit that Shalaby discloses irradiation (2.5 Mrad, see Col. 9, Example 7) for sterilization of UHMWPE products (see for example, Abstract; col. 9, lines 17-18). Shalaby specifically concentrates on chemical cross-linking of UHMWPE (see for example, Abstract; col. 6, lines 1-10 and 34-43).

Moreover, Shalaby does not disclose the method claimed by applicants, hence, Shalaby does not disclose the product made by such methods.

Therefore, Shalaby does not anticipate the claimed invention. Applicants therefore request withdrawal of the rejection based upon the '411 patent.

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<sup>\*</sup> As explained by the Court of Customs and Patent Appeals in *In re Fong*, 288 F.2d 932, 936 (CCPA 1961), a 131 declaration is sufficient if it shows a species of an invention.

***Claim Rejections - 35 U.S.C. § 103(a):***

On page 6 of the Office Action, the examiner has rejected claims 124-127 allegedly as being unpatentable over Sun *et al.* (US 5,414,049). Applicants respectfully disagree with the examiner and submit that:

Sun *et al.* also discloses a low dose irradiation (2.5 Mrad; see, for example, abstract, and col. 7, lines 57-60, col. 8, lines 5-7) for sterilization of finished or packaged products. Sun specifically suggests heat-treatment for cross-linking radiation-sterilized products (see, for example, col. 4, lines 1-9). Therefore, Sun does not provide any motivation to use high dose radiation for cross-linking in order to arrive at the claimed invention.

Applicants therefore request withdrawal of the rejection based upon the '264 patent.

***Double Patenting Rejections:***

On pages 7 to 9 of the Office Action, the examiner has provisionally rejected claims 124-127 under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over pending claims of co-pending applications serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Applicants note that these type of rejections are intended to prevent an impermissible "prolongation" of the patent term caused by multiple patents possessing claims that are obvious in view of one another. That is, the claimed subject matter must be sufficiently close that issuance of more than one patent would necessarily result in a prolonged term for the same inventive concept. Accordingly, in making an obviousness-type double patenting rejection, the examiner must indicate how the claims of the instant application to processes of making prostheses are sufficiently "obvious" over the other claims so as to result in an impermissible prolongation of patent term. See MPEP § 804 II-B (1) at 800-21-22 (Rev. 3, August 2005). Applicants


respectfully submit that the examiner has not met this burden, and therefore the rejection should be withdrawn.

Moreover, since applicants have not received any notice of allowance for any of the cited co-pending applications, the merits of this provisional rejection need not be discussed at this time. See MPEP § 822.01. Applicants further submit that upon acceptance of the claims by the examiner, the provisional obviousness-type double patenting rejection should be withdrawn.

**REQUEST**

Applicants submit that the claims are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

  
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